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14. (Twice Amended) A method for the treatment of a sinus wound comprising discharging into a sinus cavity a wound gel from a barrier aerosol vessel containing multiple doses of a wound gel.

Remarks

This Amendment is responsive to the Final Office Action mailed February 11, 2002. Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-6, 8-10, 13-15, and 17-20 were pending. Claims 1-6, 8-10, 13-15, and 17-20 stand rejected.

It is believed that entry of this Amendment is timely filed with the appropriate payment included. Notwithstanding, Applicants hereby authorize the Commissioner to charge any additional claim fees required by entry of this Amendment to Deposit Account No. 04-0480.

Claims 13 and 14 have been amended to more clearly recite the present invention. Support for this amendment is apparent. Thus, no new matter is added.

Claim Rejections under 35 U.S.C. §103(a)

In formulating the various rejections set forth below the Office appears to have worked from a basic misunderstanding of the invention. Numerous documents are cited that recite aerosol formulations in which a liquid is driven out of an aerosol device by gas, with in some cases, a gel forming as the output product. The Office cites an aerosol device as if it had the impression that such citation is enough to anticipate the aerosol device element of the claims. However, this is in error: The device of the claims is a barrier aerosol vessel, which (as is understood in the art and described in the specification at page 2) is a device wherein the substance to be dispensed is in one container and the propellant is in another container, with the two separated by a flexible barrier that allows the propellant to exert its expelling force on the substance.

Applicant reminds the Office that in formulating rejections under 35 U.S.C. §103, it has been often cautioned to take precautions to assure that its view that a combination or modification of the art is "obvious" is not tainted by having learned what now seems apparent

from the Applicant's specification. One of the safeguards against this type of "hindsight reconstruction of the invention" is that the art must provide evidence of a motivation to make the combination or modification. To find such motivation to combine or modify in the prior art, that prior art must provide evidence that the combination or modification would have been viewed as desirable in the context of the prior art teachings. See MPEP 2143.01. This desirability must be evidenced by more than a mere conclusion that the alleged combination is feasible. *Id.*

Relatively recently, in *Winner Int'l Royalty Corp. v. Wang*, the Federal Circuit applied this desirability standard to uphold the validity of claimed subject matter where different references separately disclosed each element of a claimed invention. *Winner*, 202 F.3d 1340, 53 USPQ2d 1580 (Fed. Cir. 2000), *cert. denied*, 530 US 1238. In *Winner*, the claims at issue were directed to a "Club"-like automobile anti-theft device locked in place across a steering wheel by a self-locking, ratcheting mechanism. References presented at trial disclosed (1) a similar anti-theft device that used a dead-bolt mechanism instead of the ratcheting mechanism, (2) a "Y-shaped" anti-theft device mounted on the steering wheel that used a ratcheting mechanism and (3) other pedal-mounted anti-theft devices that can accommodate either a ratcheting or a dead bolt mechanism. Accordingly, the Federal Circuit found that the first reference disclosed "virtually all aspects claimed" except the ratcheting mechanism. *Winner* at 1349, 53 USPQ2d at 1587. The second reference disclosed the ratcheting mechanism and the third group of references "may have informed one of ordinary skill in the art that both mechanisms would work." *Winner* at n. 7. However, the references did not suggest that one mechanism *should* be replaced with another. *Winner* at n. 7. The Federal Circuit concluded that one of reasonable skill in the art may well have not elected to trade the superior security of a dead-bolt mechanism for the superior convenience of a ratcheting mechanism: "[t]rade-offs often concern what is feasible, not what is, on balance, desirable. Motivation to combine requires the latter." *Winner* at 1349. Accordingly, the Federal Circuit held that claimed device with ratcheting mechanism was not obvious under 35 U.S.C. §103(a).

The Office should, in view of this guidance, note that none of the cited art provides the least suggestion that it would be desirable to load a gel¹ in a gas-driven dispensing device or in

¹ A gel is a colloid in which a disperse phase has combined with a continuous phase to produce a viscous jellylike product. Hawley's Condensed Chemical Dictionary, Thirteenth Edition.

particular to load a gel into a barrier aerosol container. In view of this fact, all of the rejections formulated by the Office are by definition created with improper hindsight.

Addressing specific rejections, claims 1-6, 8-10, 13-15, and 17-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over either Schmolka (U.S. Patent 4,495,168), Court et al. (EP 0 666 081), Sperry (U.S. Patent 5,059,187) and/or Tipton (EP 0 560 014). Applicants disagree and submit that even assuming, *arguendo*, all of the Examiner's assertions are true, none of the cited references, either alone or in combination, teach or suggest a barrier aerosol vessel containing multiple doses of wound gel, used in the treatment of a variety of wound types, where contamination of the gel is minimized once the packaging is opened.

A. Schmolka

Claims 1 and 13 were rejected as unpatentable over Schmolka. In the Office Action, the Examiner alleged that Schmolka "teaches a pressurized gel composition in an aerosol container....[t]he composition comprising water and glycol" and therefore the present invention is obvious. Applicants disagree. The invention claimed in Schmolka and the present invention differ in at least two significant ways - differences which are not taught or suggested by Schmolka. The distinguishing characteristics of the present invention are such that the present invention would not have been obvious at the time invention was made to a person having ordinary skill in the art.

One significant difference between the present invention as claimed and Schmolka is that the composition claimed in the present invention, as discussed at length above, is in gel form while stored in the aerosol container and remains in gel form when contacted with a wound surface. The composition in Schmolka, however, is in liquid form in the container, but forms a gel upon being contacted with tissue. The specification in Schmolka teaches away from the present invention, dismissing the idea that a wound-treating material that is in a gel form while stored in the container can be effectively dispensed onto a wound, stating "[t]he filling problems inherent in the use of gels in aerosol containers...are overcome in accordance with the instant invention by the use of a pressurized composition which may be sprayed from an aerosol container and which is liquid inside the container and forms a gel on contact with living tissue." *See Schmolka*. This statement shows that the general thinking among those skilled in the art is that a wound gel that is in gel form inside the vessel would be difficult, if not impossible, to properly dispense. In addition, the statement shows that Schmolka does not anticipate an aerosol

vessel containing multiple doses of wound gel (which is in gel form inside the container). Thus, the present invention allows for the storage of a wound treatment material in gel form - allowing for the use a number of wound-treating gels.

A second major difference between the present invention and Schmolka is that the present invention claims an aerosol barrier vessel where there is positive pressure in the container - making the vessel self-sealing - which aids in the maintenance of product sterility. This allows the present invention to dispense multiple doses while the risk of contamination of the gel is minimized. The invention in Schmolka is not self-sealing, thus it does not claim to have such a quality. Thus Schmolka does not anticipate an aerosol barrier vessel that is in gel form in the container or is self-sealing as to minimize product sterility. Withdrawal of rejection under 35 U.S.C. §103(a) is respectfully requested.

B. Court et al. and Sperry

Claims 1-6, 8-10, 13, 15, 17-20 were rejected as unpatentable over Court in view of Sperry. In particular, the Examiner alleged

[Court et al] is teaching gel wound dressing The wound dressing is packaged and sterilized. The gel composition of the reference can be extruded in the form of gel onto gauze. However, [Court] does not teach the method of making the aerosol vessel.

[Sperry] is teaching [a] method for providing an aerosol container and method for cleaning the wound including introducing the wound cleaning solution through an opening into a pouch and then the opening is closed by a valve, the container is then sterilized and the propellant is introduced into the can.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to include the gel composition of Court in the aerosol vessel of Sperry, motivated by the teaching of Sperry that the rigid container of the aerosol is adapted to withstand a high pressure, with reasonable expectation of success of treating wounds by delivering gel composition from an aerosol vessel.

Applicants disagree. Sperry and Court, either combined or separate, do not teach or suggest that which is claimed in the present invention. While Court does disclose a gel, Sperry does not provide that which is missing in Court - namely a method of and vessel for safely and efficiently dispensing multiple doses of wound-treating gel where the gel is in gel-form in the container and the vessel's inherent self-sealing characteristic minimizes contamination of the gel after the dispensing vehicles initial use.

Sperry teaches away from the present invention in two important ways. First, Sperry does not teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material. Instead, Sperry teaches away from a multiple dose container stating that in the specification, describing the invention as “the container and method...[is such that] the container contains enough wound cleaning solution to irrigate the average wound or abrasion.” See *Sperry*, column 1, lines 52-56. Thus, although the contents of the container in Sperry can be sterilized, Sperry does not disclose a dispensing device that can contain more than a single dose of wound-treating material. The present invention discloses a multi-dose gel package that is designed so as to minimize contamination once the package is opened. Thus, nothing in Sperry suggests a wound gel dispenser capable of dispensing multiple doses while keeping the wound gel contents reasonably free of contaminants.

A second way in which Sperry teaches away from the present invention is in the fact that Sperry discloses a method of dispensing liquid, not gel, to a wound. Numerous other inventions disclose wound treatment methods that employ the dispensing of liquids and liquid that convert to gel on contact with tissue. However, the present invention differs in that the wound-treating composition is in gel-form inside the container. Sperry teaches a method of dispensing a wound treatment material that is in liquid form while in the container and while being dispensed - a method that lacks the complicating factors of dispensing a gel that is in gel-form within the container.

Thus, neither Sperry nor Court teach or suggest that which is disclosed in the present invention. Thus, withdrawal of rejection under 35 U.S.C. §103(a) is respectfully requested.

C. Sperry and Tipton

Claim 14 was rejected as unpatentable over Sperry and Court in view of Tipton. In particular, the Examiner states

The teachings of [Court] by itself in view of [Sperry] discussed above [d]o not teach the treatment of the sinus wound.

[Tipton] disclos[es] a spray apparatus includes a vessel with a dispensing means which can be a valve and nozzle mechanism and it contain[s] a composition which can be administered to the skin, mucous membrane of the mouth and the nose (sinuses), tissue injury (wound), or body cavity (sinuses). The composition contains polyethylene glycol and propylene glycol (wound gel disclosed by the applicants).

It is obvious to one having ordinary skill in the art at the time of the invention to use an aerosol containing the gel composition of [Court et al.] to treat [a] sinus wound, motivated by Tipton[']s teaching that sprayed dressing can be applied to body cavities, with reasonable expectation of success of delivering the wound healing gel to the sinuses.

Applicants disagree. To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (1970). If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *See In re Fine*, 837 F.2d 1071 (Fed Cir. 1988); *see also* MPEP 2143.30.

Applicants disagree with the Examiner that claim 1 is unpatentable over Court in view of Sperry, as explained above. As such, Applicants submit that claim 1 is nonobvious. Thus, *In re Fine* provides that any claim which is dependent on claim 1 (such as claim 14), must be deemed nonobvious under 35 U.S.C. §103(a). Moreover, however, nothing in Tipton discloses or suggests the desirability of delivery composition to the wound via a barrier aerosol device.

Based on the arguments made above, Applicants respectfully request withdrawal of rejection under 35 U.S.C. §103(a).

FEE DEFICIENCY

☒ If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480

Serial No.: 09/341,821
Group Art Unit: 1615

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "A. E. Jackson", is written over a horizontal line. The signature is enclosed within a large, hand-drawn oval.

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Detail of claim amendments

13. (Twice Amended) A method for [the] treatment of a wound[s] comprising discharging onto the wound a wound gel from a [the] barrier aerosol vessel containing multiple doses of a [the] wound gel].

14. (Twice Amended) A method for the treatment of a sinus wound[s] comprising discharging into a sinus cavity a wound gel from a [the] barrier aerosol vessel containing multiple doses of a [the] wound gel.

Claims following entry of amendment mailed May 13, 2002

1. (Previously Amended) A barrier aerosol vessel containing multiple doses of a wound gel for the treatment of wounds.
2. (Unchanged) A vessel as claimed in claim 1 wherein the gel comprises a hydrocolloid.
3. (Previously Amended) A vessel as claimed in claim 1 wherein the gel comprises a natural gelling agent.
4. (Previously Amended) A vessel as claimed in claim 1 wherein the gel comprises a glycol.
5. (Previously Amended) A vessel as claimed in claim 1 wherein the gel comprises:
 - (a) from about 0.05% to 10% by weight of a natural gelling agent;
 - (b) from about 1.0% to 10% by weight of a hydrocolloid;
 - (c) from about 5.0% to 30.0% by weight of an alkylene glycol; and
 - (d) at least 50% by weight of water
6. (Previously Amended) A vessel as claimed in claim 1 wherein the gel is sterile.
8. (Previously Amended) A method of making a barrier aerosol vessel comprising wound gel, the method comprising the steps of:
 - (i) filling an inner container with gel, said inner container being contained within an outer casing container;
 - (ii) sealing the inner container with an opening valve; and
 - (iii) introducing a pressure medium between the inner container and the outer casing container.
9. (Previously Amended) A method of making a barrier aerosol vessel comprising wound gel, the method comprising the steps of:
 - (i) filling an inner container with non-sterile gel, said inner container being container being contained within an outer casing container;

- (ii) sealing the inner container with an opening valve;
- (iii) sterilizing the vessel and gel contained within it; and
- (iv) introducing a pressure medium between the inner container and the outer casing container.

10. A multiple dose, sterile wound gel contained within an aerosol vessel.

13. (Twice Amended) A method for treatment of a wound comprising discharging onto the wound a wound gel from a barrier aerosol vessel containing multiple doses of a wound gel.

14. (Twice Amended) A method for the treatment of a sinus wound comprising discharging into a sinus cavity a wound gel from a barrier aerosol vessel containing multiple doses of a wound gel.

15. The method of claim 13 wherein said wound gel is sterile.

17. The method of claim 13 wherein said gel is a hydrocolloid-containing gel.

18. The method of claim 13 wherein said gel has a viscosity of between 150 and 800 Pas.

19. The method of claim 13 wherein gel-containing vessel is prepared by the following steps:

- (i) filling an inner container of said vessel with a non-sterile gel;
- (ii) sealing the inner container with an opening valve;
- (iii) sterilizing said vessel and gel; and
- (iv) introducing a pressure medium between the inner container and the outer casing container.

20. A method for dispensing multiple doses of a preservative-free therapeutic gel from a single dispenser to a wound in need of such gel comprising the steps of:

- a) providing a barrier aerosol dispenser with said gel therein by
 - (i) preparing said barrier aerosol dispenser to comprise an inner container and an outer casing container;

- (ii) filling said inner container with said gel
 - (iii) sealing said inner container with an openable and closeable dispensing valve;
 - (iv) sterilizing the container and gel therein;
 - (v) introducing a pressure medium between said inner container and said outer casing container; and
- b) opening and closing said dispensing valve to dispense two or more doses of said gel into said wound, whereby the risk of contamination of the gel remaining in said dispenser is substantially eliminated.